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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/455,543

12/07/99

DESSETTE

B

45-110-045

HM12/1010

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EXAMINER

PATENT

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/455,543

Applicant(s)

Bessette et al.

Examiner

Patricia Patten

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 31, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 2, and 5-16 is/are pending in the application.
- 4a) Of the above, claim(s) 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-14, and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-2 and 5-16 are pending in the application.

Applicants elected the species cAMP/cAMP-dependent protein kinase inhibitors and eugenol.

This application contains claim 15 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-14 and 16 were presented for examination on the merits.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2 and 5-16 are <sup>now</sup> provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 09/455,544. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are all drawn to a composition comprising a plant essential oil compound such as eugenol along with a signal transduction modulator such as cAMP.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The Office acknowledges that Applicants have confirmed that the Double Patenting rejection set forth in the Office Action dated 1/30/01. Applicants have relayed that a terminal disclaimer will be filed upon allowance, however, until that time, the rejection remains standing.

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*Claim Rejections - 35 USC § 112*

Claims 1-2 and 5-14 remain rejected, and new claim 16 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising a plant essential oil compound which is known in the art for treating cancer or abnormal cell proliferation, such as monoterpenes (eugenol), along with growth factor receptor inhibitors such as FGF inhibitor, does not reasonably provide enablement for any plant oil compound or any plant oil compound specifically recited in the Markush Group of plant essential oil compounds in Claim 1, in combination with a signal transduction modulator such as cAMP or cAMP-dependent protein kinase, tyrosine kinase, calcium phospholipid-dependent protein kinase, mitogen activated protein kinase family members or calcium-calmodulin-dependent protein kinase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants' arguments filed 7/31/01 were considered, but not found persuasive.

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Applicants have cited case law: 'In describing the claimed invention, the Applicants are not required to explain every detail since they are speaking to those of ordinary skill in the art' and further that "Thus, a patent may be enabling even though some experimentation is necessary, as long as the amount of the experimentation is not unduly fair."

In the instant case, it was deemed that because cAMP and/or cAMP dependant protein kinases were not found in the prior art for decreasing cell proliferation, the invention is improbable, as well as uncertain due to lack of guidance in the Instant specification. Further, in the present instance, the claimed invention encompasses a veritable plethora of possible combinations of compounds of diverse structure and type. The inadequate disclosure coupled with a lack of representative examples and the art recognized unpredictability with respect to the effects of bioactivity of the underlying compounds (besides the compounds deemed to be enabled, ie; eugenol and FGF for example), thus preclude the use of compounds within the scope of the presently claimed invention by the skilled artisan without undue experimentation.

Applicants argue that the examples in the specification 'exemplify preferred embodiments of the claimed invention' however, do not point out specific embodiments embedded within the Instant specification which would necessarily substantiate the scope of the claimed invention for the intended use. Thus, the rejection stands for the reasons set forth in the Office action dated 7/31/01 as well as the reasoning set forth *supra*.

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No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

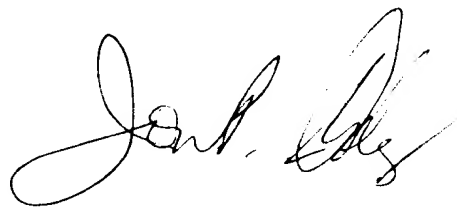
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Jan. P. [unclear]", located in the lower right quadrant of the page.